EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY LITIGATION MDL NO. 2327

THIS DOCUMENT RELATES TO ALL CASES

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

VIDEOTAPED DEPOSITION OF
CHARLOTTE OWENS, M.D.

VOLUME 1

Atlanta, Georgia

Wednesday, June 19, 2013

Reported by: MICHELLE M. BOUDREAUX, RPR
Golkow Job No. 66788

A So at that time, the medical director was responsible for contributing to the development of the devices that we were going to bring to market.

Q In what way?

A Providing either direct or indirect medical support. What I mean is either giving information back based on our own background experience or after working with consultants and key opinion leaders, who may be experts in the field. We would also review product complaints.

We would also work with the sales and marketing team to develop information that would educate them on the product and the use of the product. We would contribute to the development of what we used to call IFUs, instructions for use, patient brochures, kind of like the in-house medical person to help with issues that required an MD's attention.

Q So you had to be copied on a lot of emails. You were covering a lot of different facets within the organization.

A From time to time. You know, sometimes they would have a discussion prior to bringing you in, depending on what the situation was.

Q Look, I've seen your travel schedule. Your

contribute, but again, I don't want to give the impression that all of this was on one person.

Q No, but you were asked to contribute?

A Correct.

Q Okay. So that would be professional -- when you say "education," that's what you mean, professional education?

A But also to the sales force and, you know, others within the company.

Q So you helped with marketing?

A Yes.

Q Okay. IFU product development is what I wrote down. Is that --

A Yes.

Q And marketing, which is the -- providing the education to the sales force?

A Yes.

Q Anything else, or is that the big categories?

A I think those are the big categories.

Q All right. So you also provided information to the regulatory agencies or to the -- well, to the regulatory agencies for new products that you were bringing to the market, correct?

A Yes.

using the hammock style, and half are performing it in the U-style, the obturator style. Do you follow me?

A I don't recall that at all.

Q All right. That's just awful, awful. I'll get back to the training question.

A Okay.

Q Now, did you validate -- did you participate in validating -- participating in validation studies for the IFU?

MR. BROWN: Objection.

Q (By Mr. Keith) In regards to the TVT-Secur?

A So for the IFU, the -- you know, the instructions for use were based on a lot of different things, not just a study, but pretty much the design of the product, key ways to use the device that would enable the practitioner to place it as it was, you know, intended to. So that may or may not be associated with a validation study.

Q All right. So here's my understanding, you have an IFU --

A Yes.

Q -- okay? Did you participate in drafting IFUs while at Gynecare?

A Yes.

Q What products?

A I remember Prolift. I do not believe I was a part of the TVT-Secur, nor the TVT Obturator.

Q All right. So we have a draft of an IFU, Gynecare has come up with this, and then my understanding is we've got to validate this IFU, this instruction for use, and that's what that stands for, that the doctors can actually read that and then complete the procedure based upon the reading of the IFU. Do I understand that correctly?

A You do.

Q Okay. And the validation study, that's what that's for?

A Correct.

Q Okay. All right. So your memory is you don't believe you did any of that in regards the TVT-Secur?

A Or the TVT Obturator.

Q Okay. The only one that you may have developed protocol for was the Prolift?

A Correct.

Q Okay. What about clinical expert reports, did you -- was that part of your responsibility?

A Yes.

requirement around the world for you to submit your protocols to institutional review boards or ethics committees, whose primary focus is on the safety of the patient.

Q Was ethics something important to you?

A Absolutely.

Q Okay. Was it important to you during your time at Gynecare?

A Absolutely.

Q Still important to you?

A Absolutely.

Q Okay. Was safety your first responsibility as the medical affairs director?

A Yes.

Q Okay. Did you -- as medical affairs director, was your first priority to ensure the safety of the patient and protect the patient?

A Yes.

Q Okay. Now, you also, as part of your responsibilities, if I understand correctly -- you called it something else. I call it defense of device. I can't remember what you called it, review product complaints. Part of your responsibility was to defend the devices or complaints against the device that were

lodged by patients or doctors, correct?

MR. BROWN: Objection.

THE WITNESS: I'm not sure I like the term "defend."

MR. KEITH: I didn't figure you would, but I -- but it is what it is. But you were responsible --

THE WITNESS: For reviewing --

MR. KEITH: -- for responding to accusations against the company that were lodged by either patients or their doctors?

MR. BROWN: Objection.

THE WITNESS: My -- I wouldn't even say people accused or made accusations. What would happen is we might hear of an -- of an adverse event, we might be informed in writing of an adverse event, we may see in literature that there were adverse events, and then we would evaluate whether or not they were attributable to the device or some other factor.

Q (By Mr. Keith) Dr. Owens, to be fair to me --

A Right.